6. 510(k) Summary

This 510(k) summary information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT:	ReFlow Medical
DATE PREPARED:	August 1, 2013
CONTACT PERSON:	Rebecca K Pine ReFlow Medical 1003 Calle Sombra San Clemente, CA 92673 Phone: (760) 809.5178
TRADE NAME:	Wingman Extendable Tip Support Catheter
COMMON NAME:	Guide Catheter
CLASSIFICATION NAME:	Percutaneous Catheter
DEVICE CLASSIFICATION:	Class 2, per 21 CFR 870.1250
PRODUCT CODE	DQY

SEP 19 2013

PREDICATE DEVICES: Wingman Extendable Support Catheter (K120178)

Substantially Equivalent To:
The modified Wingman Extendable Tip Support Catheter is substantially equivalent in intended use, principal of operation and technological characteristics to the Wingman Extendable Support Catheter cleared under premarket notification K120178.

Description of the Device Subject to Premarket Notification:
The Wingman Extendable Tip Support Catheter is a device intended to provide additional support to a steerable guidewire when accessing discrete regions of the peripheral vasculature. The device consists of a support catheter, with a concealed radiopaque beveled guide-tip, and activating handle. The through-lumen of the device can serve as a conduit for the delivery of diagnostic and therapeutic agents.

Indication for Use:
The Wingman Extendable Tip Support Catheter is intended to be used in conjunction with steerable guidewires to access discreet regions of the peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices and provide a conduit for the delivery of saline solutions or diagnostic/therapeutic agents.

Technical Characteristics:
The modified Wingman Extendable Tip Support Catheter has similar physical and technical characteristics to the predicate device. The modified Wingman and predicate Wingman devices differ in the following:

- Product line extension; new lengths: 65cm, 150cm
- Modified strain-relief

Performance Data:
All necessary testing has been performed for the Wingman Extendable Tip Support Catheter to assure substantial equivalence to the predicate device and demonstrate the device performs as intended. All testing was performed on test units representative of finished devices.

The device design was qualified through the following tests:

- Simulated Use
- Tensile Strength
- Torque
- Pressure Test
- Coating/Plating verification
- Corrosion Test
- Dimensional verification and visual inspections

The modified Wingman Extendable Tip Support Catheter met all specified criteria and did not raise new safety or performance questions.

Basis for Determination of Substantial Equivalence:
The Indication/Intended Use and the fundamental scientific technology of the modified device have not been changed and are the same as those described in the unmodified predicate device. The modified Wingman Extendable Tip Support Catheter is determined by ReFlow Medical, to be substantially equivalent to the Wingman Extendable Tip Support Catheter (K120178).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 19, 2013

Reflow Medical, Inc.
c/o Ms. Rebecca K. Pine
Head of Regulatory Affairs/Quality Assurance
1003 Calle Sombra
San Clemente, CA 92673

Re: K132420
Trade/Device Name: Wingman Extendable Tip Support Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: August 1, 2013
Received: August 5, 2013

Dear Ms. Pine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 5 **Indications for Use Statement**

5. Indications for Use Statement

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): _____

Device Name: **Wingman Extendable Tip Support Catheter**

Indications for Use:

The Wingman Extendable Tip Support Catheter is intended to be used in conjunction with steerable guidewires to access discreet regions of the peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices and provide a conduit for the delivery of saline solutions or diagnostic/therapeutic agents.

AND/OR

Prescription Use __X___
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use_____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bram D. Zuckerman -S
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